Remarks

Summary of pending claims

Upon entry of the present amendments, claims 24-28, 31-33, 36-38, 41-48, 41-48, and 51-53 will be pending. Claims 1, 13, 16-20, and 22 are cancelled without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of the cancelled claims in future divisional or continuation applications. Claims 29, 30, 34, 35, 39, 40, 49, and 50 are hereby amended. No new matter has been added by way of the present amendment.

Rejection under 35 U.S.C. § 101/ 112, first paragraph

Claims 24-53 were rejected under 35 U.S.C. § 101 for allegedly lacking patentable utility. *See*, Paper No. 13, page 3, paragraph 7. More specifically, as stated in Paper No. 13, page 3, paragraph 8, "the Examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter." Applicants respectfully disagree and traverse.

Applicants respectfully point out that, according to the M.P.E.P., the burden is on the Examiner to establish that it is more likely than not that a person of ordinary skill in the art would not consider the utility asserted by Applicants to be specific, substantial, and credible. *See* M.P.E.P. § 2107 at 2100-30. Thus, the Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *Id.* at 2100-40. The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the Applicants' assertion of utility. *See id.*; *See also In re Brana,* 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). For the reasons set forth below, the Examiner has not met the burden that is necessary to establish and maintain a rejection of claims 24-53 for lack of utility under 35 U.S.C. § 101.

In order to find that an asserted utility is not specific or substantial, the burden is on the Examiner to make a *prima facie* showing that it is more likely than not that a person of ordinary skill in the art would not consider any utility asserted by the Applicant to be specific or substantial. *See* M.P.E.P. § 2107.02(IV); Utility Examination Guidelines, 66 FR 1092, January 5, 2001 at 1098, col. 3 (emphasis added). Such a *prima facie* showing must contain (1) an explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established; (2) support for factual finding relied upon in reading this conclusion; and (3) evaluation of all relevant evidence

of record, including utilities taught in the closest prior art. *See id.* In the present case, the Examiner has simply stated that "Applicants have failed to provide *specific* and *substantial* disclosure that this gene activates the EGR1 pathway in cells that are not from cell lines (emphasis original)." *See,* Paper No. 13, paragraph 9 at page 4. Importantly, no evidence or reasoning is provided as to why the skilled artisan would not consider the utility asserted by Applicants to be specific and substantial based on the teachings in the specification. Thus, the Examiner has not met the burden required to maintain a utility rejection under 35 U.S.C. § 101.

Notwithstanding the above discussion, Applicants contend that, contrary to the Examiner's allegations, Applicants have set forth in the specification statements that clearly provide the specific, substantial, and credible asserted utility that the Examiner contends is lacking. For example, Applicants disclose that the gene, which encodes the polypeptide of the invention (SEQ ID NO: 142), is primarily expressed in osteoclastoma tissues. Based in part on this tissue expression, Applicants assert that polypeptides and antibodies of the invention would be useful as immunological probes for the differential identification of osteoclastoma tissue, and, therefore, would have utility as an osteoclastoma cancer diagnostic. *See, e.g.,* specification at page 121, line 21 to page 122 line 12).

This asserted utility is specific and substantial. First, the disclosed use of the polypeptides of the invention is not generally applicable to all proteins. For instance, all proteins are not useful in providing immunological probes for differential identification of osteoclastoma tissue. The fact that the claimed polypeptide is overexpressed in osteoclastoma tissue as opposed to normal bone tissue demonstrates a specific utility as an osteoclastoma tumor diagnostic marker. Second, the use of the claimed polypeptides to diagnose osteoclastoma is certainly a "real world" use and, therefore, is a substantial utility.

Moreover, while the Examiner has neither explicitly discussed the credibility of the asserted utilities nor provided Applicants evidence or reasoning undermining the credibility of the asserted utilities, Applicants submit that, in light of the teachings of the specification and in view of what was known at the time the invention was filed, one of ordinary skill in the art would have found the Applicants' asserted utility to be more likely than not true, and therefore, the Applicants' asserted utility is credible. As discussed *supra*, in assessing the credibility of the asserted utilities, the burden is on the Examiner to establish why it is more likely than not that one of ordinary skill in the art would doubt *(i.e.,* "question") the truth of the statement of utility. M.P.E.P. § 2107 at 2100-30 and 2100-40. Thus, the Examiner must provide evidence sufficient

to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *Id.* The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the Applicants' assertion of utility. *See Id.*; *see also, In re Brana,* 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995).

Applicants submit that, for the reasons stated above, the utility asserted in the specification for Protein HOSDK95 is indeed *specific, substantial and credible.* Accordingly, Applicants respectfully submit that the rejection of claims 24-53 under 35 U.S.C. § 101 has been obviated. Applicants respectfully request that the rejection of claims 24-53 under 35 U.S.C. § 101 be reconsidered and withdrawn.

The claims have also been rejected under 35 U.S.C. § 112, first paragraph (see page 5 of Paper No. 13). For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a specific, substantial and credible asserted utility. The Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. §101 rejection is proper." M.P.E.P. § 2107 (IV) at 2100-36. Therefore, because the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejections under 35 U.S.C. § 112, first paragraph, based on the alleged lack of utility of the claimed invention, should be withdrawn. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 24-28, 34-38, and 44-48 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *See*, Paper No. 13, page 5, paragraph 10. More specifically, the Examiner states that the "amended subject matter in these claims is considered to be new matter because they are not disclosed in the original specification." *See*, Paper No. 13, page 5, paragraph 10. Applicants respectfully disagree and traverse.

As one of the asserted uses for the polypeptides of the invention is, *e.g.*, a tool to diagnose osteoclastoma, Applicants point the Examiner's attention to the fact that the full-length, as well as the mature protein could be used. Based on statements made by the Examiner, it appears that the Examiner has concluded that the polypeptides having an amino acid sequence

of residues 1-54 and 2-54 of SEQ ID NO: 142 are new matter because Table 1, row 7 at Pages 121-122 of the specification shows that the secreted portion of the polypeptide of sequence SEQ ID NO: 142 is only one residue long. *See*, Paper No. 13, page 5, paragraph 11. Applicants respectfully point out that the specification clearly discusses that polypeptides of the invention can be, for example, recombinantly produced in different host systems (*e.g.*, mammalian and bacterial cells) or even synthetically manufactured. *See*, specification page 144, lines 13-24. It is well known in the art that a recombinantly expressed polypeptide may or may not be processed (*e.g.*, glycosylated, cleaved) depending on the expression system chosen. *See*, specification page 178, line 29 to page 179, line 10. Therefore, Applicants have provided ample support for full-length as well as secreted proteins. Furthermore, Applicants respectfully point out that only full-length polypeptides are presently claimed. Therefore, the polypeptides consisting of residues 1-54 or 2-54 of SEQ ID NO: 142 are not new matter. Applicants respectfully request that the rejection of claims 24-28, 34-38, and 44-48 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

[A] Claims 24-53 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to point out and distinctly claim the subject matter which the applicant regards as the invention. *See*, Paper No. 13, page 6, paragraph 14. More specifically, the Examiner states that the "after the removal of the signal peptide the functional secreted protein of the SEQ ID NO: 142 is one amino acid, number 54." *See*, Paper No. 13, page 6, paragraph 15. Applicants respectfully disagree and traverse.

As stated above, Applicants disclose and claim the full-length protein, *i.e.*, amino acid 1-54 or 2-54 of SEQ ID NO: 142, therefore, there is no conflict between the disclosure in Table 1, row 7 and claim 24. Applicants respectfully request that the rejection of claims 24-53 under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

[B] Claims 29, 30, 39, 49, and 50 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to point out and distinctly claim the subject matter which the applicant regards as the invention. *See*, Paper No. 13, page 6, paragraph 16. More specifically, the Examiner states that the claims "contain abbreviations, such as ATCC,

that cause the claims to be vague and indefinite unless accompanied by the full name in parentheses." *See*, Paper No. 13, page 6, paragraph 16.

Applicants respectfully disagree and traverse, but, in the interest of prosecution, claims 29, 30, 39, 49, and 50 were amended as suggested by the Examiner. Applicants respectfully request that the rejection of claims 29, 30, 39, 49, and 50 under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

[C] Claims 34-43 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to point out and distinctly claim the subject matter which the applicant regards as the invention. *See*, Paper No. 13, page 6, paragraph 17. More specifically, the Examiner states that the "sequence limitations are confusingly reasonably interpretable in two very different ways." *See*, Paper No. 13, page 6, paragraph 17.

Applicants respectfully disagree and traverse. However, in the interest of prosecution, claims 34, 35, 39, and 40 have been amended in such a way as to obviate the Examiner's rejection. Applicants respectfully request that the rejection of claims 34-43 under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 102(b)

Claims 34-37 and 39-42 were rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by the Sigma Catalog (1990). *See*, Paper No. 13, page 7, paragraph 2. More specifically, the Examiner states that the "invention disclosed in the Sigma Catalog anticipates the limitation of a first polypeptide at least 90% or 95% identical to a second consisting of amino acid residues 1-54 of SEQ ID NO: 142 or consisting of the complete polypeptide encoded by the HOSDK95 cDNA." *See*, Paper No. 13, page 7, paragraph 3.

Applicants respectfully disagree and traverse.

Preliminarily, Applicants point out that the rejected claims contain "consisting of" language.

Applicants respectfully point out that the M.P.E.P. states:

> "[A] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a

> single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQD2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQD2d 1913, 1920 (Fed. Cir. 1989).

M.P.E.P., 8th Edition, § 2131 (August 2001). Furthermore, Applicants assert that a fair reading of the specification would allow one skilled in the art to conclude that the polypeptide FL (Phenylalanine-Leucine) Product Number P03876 (page 802) is not 90% or 95% identical to a polypeptide consisting of amino acid residues 1-54 of SEQ ID NO: 142 or consisting of the complete polypeptide encoded by the HOSDK95 cDNA. Indeed, the specification at page 149, line 22 to page 151, line 17, teach how to determine the percentage of identity of a query polypeptide as compared to a reference polypeptide of the invention. If one of skill in the art were to apply the method described in the specification, the overall homology of the Sigma polypeptide with the polypeptide of amino acid sequence SEQ ID N: 142 would be insignificant. Additionally, Applicants assert that the amendments introduced to claims 34, 35, 39, and 40 obviate the Examiner's rejections of claims 34-37 and 39-42. Therefore, Applicants respectfully request that the rejection of claims 34-37, and 39-42 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Conclusion

Entry of the above amendment is respectfully solicited. In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: March 3, 2003

Respectfully submitted,

By _____
Janet M. Martineau
Registration No.: 46,903
HUMAN GENOME SCIENCES, INC.
9410 Key West Avenue
Rockville, Maryland 20850
(301) 315-2723

KKH/JMM/SA/FR/ba

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ruben et al

Docket No.: PZ011

Application No.: 09/776,724

Group Art Unit: 1631

Filed: February 6, 2001

Examiner: C. Ly

For: Human Protein HOSDK95 (as amended)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

29. (Once amended) An isolated protein comprising the amino acid sequence of the complete polypeptide encoded by the HOSDK95 cDNA contained in ATCC **(American Type Culture Collection)** Deposit No. 209141.

30. (Once amended) The isolated protein of claim 29 which comprises the amino acid sequence of the complete polypeptide encoded by the HOSDK95 cDNA contained in ATCC **(American Type Culture Collection)** Deposit No. 209141, excepting the N-terminal methionine.

34. (Once amended) An isolated [~~first~~] polypeptide at least 90% identical to a [~~second~~] polypeptide consisting of amino acid residues 1 to 54 of SEQ ID NO:142.

35. (Once amended) The isolated polypeptide of claim 34, wherein said [~~first~~] **isolated** polypeptide is at least 95% identical to [~~said second polypeptide~~] **the polypeptide consisting of amino acid residues 1 to 54 of SEQ ID NO: 142**.

39. (Once amended) An isolated [~~first~~] polypeptide at least 90% identical to a [~~second~~] polypeptide consisting of the complete polypeptide encoded by the HOSDK95 cDNA contained in ATCC **(American Type Culture Collection)** Deposit No. 209141.

40. (Once amended) The isolated polypeptide of claim 39, wherein said [~~first~~] **isolated** polypeptide is at least 95% identical to [~~said second polypeptide~~] **the polypeptide consisting of the complete polypeptide encoded by the HOSDK95 cDNA contained in ATCC (American Type Culture Collection) Deposit No. 209141**.

49. (Once amended) An isolated protein consisting of at least 30 contiguous amino acid residues of the complete polypeptide encoded by the HOSDK95 cDNA contained in ATCC **(American Type Culture Collection)** Deposit No. 209141.

50. (Once amended) The isolated protein of claim 49 which consists of at least 50 contiguous amino acid residues of the complete polypeptide encoded by the HOSDK95 cDNA contained in ATCC **(American Type Culture Collection)** Deposit No. 209141.